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Response to restriction requirement in connection with U.S.S.N. 10/053,662.

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**OGILVY  
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5/17/03**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**In re application of: **John Baird et al.**Serial No.: **10/053,662**

1653 /annie

Filed: **January 24, 2002**For: **ISOLATION OF THE LAMIN  $\gamma$ 2 GENE IN HORSES AND ITS USE IN  
DIAGNOSTIC JUNCTIONAL EPIDERMOLYSIS BULLOSA**Our File.: **P84-US4****RESPONSE TO RESTRICTION REQUIREMENT**Commissioner of Patents and Trademarks  
Washington, D.C. 20231

Sir:

This is in reply to the Restriction Requirement dated April 18, 2003.

The Examiner has indicated that restriction in the present application to one of the following inventions is required under 35 U.S.C. 121:

- I. Polynucleotides, constructs, kits and method of making equine laminin  $\gamma$ 2 protein (claims 1-5, 9-11 and 15);
- II. Equine laminin  $\gamma$ 2 protein (claims 6-8);
- III. Method of diagnosing epidermolysis bullosa by identifying laminin  $\gamma$ 2 nucleic acid (claim 12-14 and 19);
- IV. Method of diagnosing epidermolysis bullosa by screening for laminin  $\gamma$ 2 protein (claim 17, 18 and 20); and
- V. Antibodies (claim 16).

Applicant respectfully traverses the foregoing claim restrictions for the following reasons.

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At the outset, the Examiner alleges that the claims of Group I and II relate to two different inventions because the process as claimed in Group I can be used to make other proteins and because the laminin protein as claimed can be made by another process. Applicant respectfully points out that the process as claimed requires expression of a construct comprising laminin  $\gamma$ 2-encoding polynucleotides. Expression of such a construct will not yield any other protein except for that defined in the claims of Group II. Moreover, Applicant also points out, with respect, that the laminin protein as claimed is not made by a materially different process in nature as alleged by the Examiner. The process by which the laminin protein is made in nature is the same as the process by which it is made recombinantly, and involves the process steps of transcription followed by translation. These process steps are both required whether protein synthesis occurs naturally or recombinantly. Accordingly, Applicant respectfully submits the restriction of claims into Groups I and II is improper and requests the Examiner to reconsider and withdraw this restriction.

The Examiner also alleges that Groups I and III define distinct inventions. In view of the comments set out above with respect to the claims of Groups I and III, (i.e. that the process of making and the product are not distinct), the Examiner is respectfully directed to 37 CFR 1.141 (b) which states:

*(b) Where claims to all three categories, product, process of making, and process of use, are included in a national application, a three way requirement for restriction can only be made where the process of making is distinct from the product. If the process of making and the product are not distinct, the process of using may be joined with the claims directed to the product and the process of making the product even though a showing of distinctiveness between the product and process of using the product can be made.*

In view of the foregoing, Applicant respectfully submits that the restriction of the claims of Groups I, II and III is improper and the Examiner is requested to reconsider and withdraw the

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restriction requirement in connection therewith.

In the event that the Examiner maintains the restriction of the claims of Groups I, II and III, Applicant wishes to elect, with traverse, the claims of Group II, i.e. claims 12-14 and 19.

Authorization is hereby made to charge any required fees to the Deposit Account No. 195113. Charge any additional fees required by this paper or credit any overpayment in the manner authorized above.

Applicant awaits an Action on the merits.

Respectfully submitted,

  
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Date: May 15, 2003

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